DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-028/S-005

Novo Nordisk Pharmaceuticals Inc.
Attention: Barry Reit, Ph.D.
Vice President, Regulatory Affairs and Quality Assurance
100 College Road West
Princeton, NJ 08540-7810

Dear Dr. Reit:

Please refer to your supplemental new drug application dated November 21, 2003, received November 24, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Velosulin BR (buffered regular human insulin [rDNA origin] injection).

This "Changes Being Effected" supplemental new drug application provides for a sticker to be attached to vial carton label notifying patients of Velosulin BR discontinuation.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on November 21, 2003.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Julie Rhee, Regulatory Project Manager, at (301) 827-6424.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
Director
Division of Metabolic
and Endocrine Drug Products, HFD-510
Office of Drug Evaluation II
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Mary Parks
5/24/04 11:08:11 AM
for Dr. Orloff